C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
[in Accordance with SMDA of 1990]

K003612

Microspeed EC Motorsystem

November 21, 2000

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Establishment Registration Number: 2916714

CONTACT: Joyce Thomas, Director Regulatory Affairs & Quality Assurance
800/258-1946 x 5076 (phone)
610/231-3713 (fax)

TRADE NAME: Aesculap® - Microspeed EC Motorsystem GD650 / GD653

COMMON NAME: Electric Surgical Motorsystem

DEVICE CLASS: Class II

PRODUCT CODE: 84 HBC

CLASSIFICATION: 21 CFR Section 882.4360 – Motor, Drill, Electric

REVIEW PANEL: Neurology

INDICATIONS FOR USE

Aesculap's Microspeed EC is intended for high speed cutting, sawing, drilling and manipulation of soft tissue and bone in the fields of Spine, ENT, Neuro and Maxillofacial Surgery.

DEVICE DESCRIPTION

The MicroSpeed is an electronic, high-speed motor system, which allows high-speed dissection up to 75,000rpm while also allowing low speed cutting up to 30,000rpm. The new control system reduces heating to a minimum at high torque.

The low speed motor can make use of all Aesculap Intra-handpieces (K953968) for adapted power at minimum weight. All HiLAN handpieces (K980636 and K973736) can also be used for high-speed dissection with the MicroSpeed. This allows universal use of one motor system during the entire procedure.

All functions of the MicroSpeed can be controlled from the sterile field by the foot control as well as the hand control for easy handling.

PURPOSE FOR SUBMISSION

The purpose for this submission is to gain marketing clearance for the Microspeed EC Motorsystem.

PERFORMANCE DATA

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device system. Aesculap's Motorsystem, however, complies with the following standards, which appear on the FDA list of Recognized Consensus Standards:

IEC60601-1:

International electrotechnical commission: Medical electrical equipment

part 1: general requirements for safety

IEC60601-1-2:

International electrotechnical commission: Medical electrical equipment

part 1: general requirements for safety; collateral standard: Electromagnetic compatibility – Requirements and tests

In addition, the Motorsystem meets the requirements of the following Underwriters Laboratories standard:

UL2601-1:

Underwriters laboratories; medical electrical equipment, general requirements for safety

Food and Drug Administration mandated Performance standards for electric Motorsystems are not in effect. Special controls apply to this device. Various voluntary performance standards including ASTM, ISO, QSR/CGMP and in-house SOP standards apply to this device. Additionally, Aesculap®, Inc. complies with the general controls authorized under Sections 501, 502, 510, 516, 518, 519 and 520 of the Food, Drug, and Cosmetic Act.

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Aesculap® Microspeed EC Motorsystem is essentially identical to the Stryker TPS Motorsystem (K943589), Hall MicroChoice Motorsystem (K971059), Linvatec E9000 Motorsystem (K990254), Aesculap® Microtron EC Motorsystem (K953968) and Aesculap® HiLAN pneumatic Motorsystem (K980686).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2001

Ms. Joyce Thomas
Director, Regulatory Affairs and
Quality Assurance
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K003612
Trade Name: Microspeed EC Motorsystem
Regulatory Class: II
Product Code: HBC
Dated: November 21, 2000
Received: November 22, 2000

Dear Ms. Thomas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K003612

Device Name: **Microspeed EC Motorsystem**

Indication for Use:

Aesculap's Microspeed EC is intended for high speed cutting, sawing, drilling and manipulation of soft tissue and bone in the fields of Spine, ENT, Neuro and Maxillofacial Surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003612

Prescription Use ✓ or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)